Lambert, Jason

From: Lambert, Jason
Sent: Monday, January 23, 2017 9:05 AM
To: Stralka, Daniel; Chavira, Raymond; Wetmore, Cynthia; Barton, Dana
Cc: Gatchett, Annette; Kaiser, Jonathan; Owens, Beth; Guria, Peter
Subject: RE: p-CBSA PPRTV assessment

Good morning Dan,
Based on current U.S. EPA guidance an uncertainty factor for database is applied based on the availability of information to inform hazard for a given duration and route of exposure. For example, a minimum dataset for a *low confidence chronic* RfD is a single subchronic study. In contrast, a minimum dataset for a *high confidence chronic* RfD is a chronic study in two species, a single two-generation reproductive toxicity study, and a developmental toxicity study in two species by the appropriate route of exposure (U.S. EPA, 1994; 2002). For human health assessment purposes, the only usable information in the p-CBSA database is the 32-day study (American Biogenics Corp, 1985); this clearly falls drastically short of the minimal information needed to confidently evaluate toxicity for a chronic RfD.

So, one might ask, what about the UFd of 10 for subchronic. Similar answer; there is no reliable information available to say anything about the risk of adverse health effects to potentially susceptible subpopulations (e.g., children, infants, neonates, etc.). In addition, while the 32-day study does meet our minimal exposure duration requirement for a subchronic study, only a NOAEL was identified (lack of a confident LOAEL is problematic). It should be noted that the high dose in the ABC, 1985 study seemed to be very near a tipping point in the dose-response where a LOAEL might be confidently identified. So in addition to the significant lack of toxicity information in general, EPA risk assessment guidance supports a greater UFd if it is deemed that a lower reference value might result if additional data were available; for example, if p-CBSA were dosed a little longer, or in a potentially more sensitive animal species, or if more animals were used per treatment group to improve power of the stats, etc. there might have been an opportunity to confidently identify an effect level associated with a health hazard. But since none of these situations exist for this chemical, it was prudent to also apply a UFd of 10 for subchronic RfD as well.

Keep in mind that the absence of data for an effect does not mean absence of effect. We simply do not have enough data to say yes/no on a given hazard and at what dose, thus we have to apply an uncertainty factor of 10 to quantitatively account for all the things we don't know about this chemical.

Jason C. Lambert, PhD, DABT
U.S. EPA, ORD, NCEA
26 West Martin Luther King Dr.
Cincinnati, OH 45268
(513) 569-7078 ph.
(513) 487-2539 fax
lambert.jason@epa.gov

From: Stralka, Daniel
Sent: Friday, January 20, 2017 7:54 PM
To: Lambert, Jason <Lambert.Jason@epa.gov>; Chavira, Raymond <Chavira.Raymond@epa.gov>; Wetmore, Cynthia <Wetmore.Cynthia@epa.gov>; Barton, Dana <Barton.Dana@epa.gov>
Cc: Gatchett, Annette <Gatchett.Annette@epa.gov>; Kaiser, Jonathan <Kaiser.Jonathan-Phillip@epa.gov>; Owens, Beth <Owens.Beth@epa.gov>; Guria, Peter <Guria.Peter@epa.gov>
Subject: RE: p-CBSA PPRTV assessment

Jason,

Thanks for sending this along. [redacted]

Dan

From: Lambert, Jason
Sent: Thursday, January 19, 2017 5:47 AM
To: Stralka, Daniel <Stralka.Daniel@epa.gov>; Chavira, Raymond <Chavira.Raymond@epa.gov>
Cc: Gatchett, Annette <Gatchett.Annette@epa.gov>; Kaiser, Jonathan <Kaiser.Jonathan-Phillip@epa.gov>; Owens, Beth <Owens.Beth@epa.gov>
Subject: p-CBSA PPRTV assessment

Good morning gentlemen,
It took a few weeks longer than I had originally predicted to finish this one but alas, attached is the finalized version of the PPRTV assessment for p-CBSA. I leave it to you all to share with our colleagues in CalEPA. Let us know if we can be of any further assistance.

Jason C. Lambert, PhD, DABT
U.S. EPA, ORD, NCEA
26 West Martin Luther King Dr.
Cincinnati, OH 45268
(513) 569-7078 ph.
(513) 487-2539 fax
lambert.jason@epa.gov